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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,782	07/09/2003	Hugh H. Trout III	23660-00654	8569
25243	7590	05/05/2005	EXAMINER	
COLLIER SHANNON SCOTT, PLLC			PANTUCK, BRADFORD C	
3050 K STREET, NW			ART UNIT	
SUITE 400			PAPER NUMBER	
WASHINGTON, DC 20007			3731	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/614,782

Applicant(s)

TROUT, HUGH H.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 15, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10-13, 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 3-5, 8, 13, 15, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,746,472 B2 to Frazier et al. Regarding Claims 1 and 19, Frazier discloses outer catheter (52), inner catheter (70/72/62) movable relative to the outer catheter (52). Joint (74) allows inner catheter (70) to be flexible [Fig. 3A; column 9, lines 51-54]. Member (102/100) is a penetration apparatus [Fig. 5] clearly disposed within inner catheter (70). Tip (100) of “introducer” 96 creates an aperture in tissue [column 11, lines 53-65; Fig. 6A]. Fastener (108) communicates with the suture (108) in Fig. 6A. Frazier’s apparatus can be bent [“assume an angular configuration”] when the user so chooses to move the catheter.
2. Regarding Claim 3, in some embodiments [Fig. 13, Fig. 17] the tip of the penetration apparatus (102/100/96) is hollow. Fig. 5 shows the whole member (96) receiving a suture in its lumen (therefore it is hollow).

3. Regarding Claims 4 and 5, Frazier discloses applying a plurality of tissue anchors in order to effect an anastomosis —the sealing of one hollow organ to another [column 43-50]. These anchors (92) [Fig. 5] can be considered “sealant materials” because they seal one organ to another. The anchors could also be called “occluding substances” because they occlude (that is, close or block off) the gap between separated hollow body organs.

4. Claims 1, 3, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,508,252 B1 to Berg et al. Regarding Claims 1 and 19, Berg shows penetration apparatus (262) [see column 13 lines 3-5 “262 may have cutting edges”] having a distal tip; fastener (74) [see also Fig. 27] shown “in communication with” penetration apparatus (262) in Fig. 23; inner catheter (272) or (262); outer catheter (208) [see Fig. 6]. Regarding outer catheter (208), in column 12, lines 48-51, Berg explains that “Apparatus 260...may be installed ...as described above with respect to Figures 9-13.” It is evident from the description of Fig. 9-13 that catheter 208 *remains in the body and that the fastener (74) is delivered through it*: “When catheter 208 is satisfactorily placed in aorta 10, the physician may withdraw catheter 206, cannula 202, and wire 204...” [column 7, lines 39-43]: note that catheter 208 must remain as directions were not given to remove it. See also Figures 41 and 45 for evidence that the fastener is delivered through a flexible outer catheter.

Berg’s apparatus can be bent [“assume an angular configuration”] when the user so chooses to move the catheter.

5. Regarding Claim 3, Fig. 23 shows that (262) is a hollow cored needle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4-8, 10-13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,508,252 B1 to Berg et al. in view of Publication No. 2004/0158267 A1 to Sancioff et al. Berg discloses apparatus as described above to apply fastener (70) to form the end to side anastomosis as shown in Fig. 27. Graft (15) may be synthetic and is a "prosthetic graft" [column 9 lines 27-31]. Berg only teaches using a fastener, but does not disclose the use of a glue, per se, that could be called a "sealant material." However, Sancioff teaches the principle of applying a sealant (i.e., glue/clotting agents) in order to fill in any gaps still remaining between anastomosed blood vessels connected by a clip {para. [0047]}. Sancioff teaches applying such a glue to clip (15).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to apply glue to Berg's fastener (70) in order to more fully seal the junction between the two blood vessels, as taught by Sancioff.

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7. Regarding Claims 5, 10, and 15, such a glue, called a “sealant” by Sancioff is a substance that occludes (closes off/shuts) the gaps between the vessels, see paragraph [0047].
8. Regarding Claims 6, 11, and 16, such a glue can also be called a plug, because it plugs any gaps remaining between the vessels.
9. Regarding Claim 7, 12, and 17, glue can absorb substances.
10. Claims 1, 3-8, 10-13, and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,865,791 to Whayne in view of U.S. Patent No. 5,209,741 to Spaeth. Regarding Claims 1, 8, and 13, Whayne discloses a delivery apparatus for performing a surgical procedure, including a flexible catheter (52/83), a penetration apparatus (66), and a fastener (116) in communication with (touching) the penetration apparatus [Figures 29, 32A, and 31C]. Pulling on steering mechanism (57) [see Fig. 29] causes the distal end of flexible catheter (52/83) to deflect to an angular configuration, as shown in Figure 7 of U.S. Patent No. 5,254,088 to Lundquist et al. Whayne incorporates the same steering mechanism (57) that was disclosed in this U.S. Patent No. 5,254,088 [Column 5, lines 50-54] into his device. Therefore, Whayne’s delivery apparatus will deflect just as Lundquist’s delivery device does.

Furthermore, Whayne’s device has an inner catheter (112) [Column 12, lines 1-20]. The inner catheter is movable, in that the whole assembly can be moved by the

user: Column 11, lines 59-63 explains that the user can move the whole assembly axially (distally or proximally).

Wayne does not disclose an outer catheter. However, Spaeth discloses a surgical access device designed for receiving catheters and other such medical instruments therethrough, and minimizes trauma caused to the body when such procedures are carried out [column 1, lines 7-15]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to insert Wayne's catheter (52) through Spaeth's cannula (12) in order to minimize trauma [column 2, lines 40-48] caused to the skin and subcutaneous layer while inserting Wayne's device through the skin, as taught by Spaeth. The modified Wayne device would now have an inner catheter movably disposed inside an outer catheter.

11. Regarding Claim 3, the tip of the penetration apparatus (66) of the modified Wayne apparatus is a hollow core needle [Figures 16A, 16B, 17, and 29; Column 7, lines 30-33].
12. Regarding Claims 4-6, 8, 10-12, and 15-17, Wayne, as modified, discloses a sealant material/occluding substance/plug associated with the fastener [Column 12, lines 52-55]. The sealant material/occluding substance/plug can be material such as silicone, collagen, mesh or even clotted human blood, as described in said passage.
13. Regarding Claim 7, mesh is capable of absorbing water.
14. Regarding Claim 18, Wayne, as modified, discloses a method of performing a surgical procedure at a surgical site, including advancing a delivery apparatus to the site in the body and activating the delivery apparatus to apply a fastener (116) to the

surgical site [Column 12, lines 33-45; Figures 29 and 31A]. Fastener (116) in one embodiment [Fig. 31A, Fig. 31B] secures a surgical component (suture 126) to a vessel (16/17). The atrium/heart is considered a vessel, because it holds/carries blood.

15. Regarding Claim 19, Wayne's modified delivery apparatus includes a solid core ("stylet" 118) inside of penetration apparatus (66) [Fig. 29].

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,533,762 to Kanner et al.

Publication No. 2004/0225305 to Ewers et al.

Publication No. 2004/0122453 to Deem et al.

Response to Arguments

17. Applicant's arguments with respect to claims 1, 3-8, 10-13, and 15-19 have been considered but are moot in view of the new ground(s) of rejection.
18. Examiner notes that Applicant has antecedent basis in the specification for the terminology "prosthetic graft," as recited in claim 18, and commented on in the Advisory Action of March 21, 2005.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
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April 20, 2005


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
4/30/05